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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,751	10/30/1998	OYSTEIN FODSTAD	4885.55USWO	8143

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/125,751	FODSTAD ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3,6-8,13-16,18-23 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3,6-8,13-16,18-23 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed November 24, 2003 in response to the Office Action of August 21, 2003 is acknowledged and has been entered. Previously pending claims 1, 14, 21, 27 and 28 have been amended, new claims 29-30 have been added. Claims 1, 3, 6-8, 13-16, 18-23, 25-30 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC § 112

4. Claims 3, 15, 16, 18, 19 remain rejected and claims 1, 6-8, 13-14, 20-21, 23, 25-26 are rejected under 35 USC 112, first paragraph and second paragraph for the reasons previously set forth in the Paper mailed August 21, 2003, Sections 7 and 8, pages 5 and 6 drawn to BM2.

The rejection is held in abeyance for the reasons of record.

5. Claims 27, 28 remain rejected and claims 29-30 are rejected under 35 USC 112, first paragraph and second paragraph for the reasons previously set forth in the Paper mailed August 21, 2003, Sections 10, and 11 page 7 drawn to BM7.

The rejection is held in abeyance for the reasons of record.

New Grounds of Objection

6. Claims 27 and 28 are objected to because of the following informalities: Claims 27 and 28 are improperly dependent on claims 29 and 30, respectively. 37 CRF 1.75 ©) states "When more than one claim is presented, they may be placed in dependent form in which a claim may **refer back to and further restrict a single preceding claim**. Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim". (see M.P.E.P. 608.01 (m and n). Claims 27 and 28 should be canceled and replaced

with identical claims 31 and 32 which are dependent upon claims 29 and 30 respectively. Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claims 1, 6-8, 13-14, 20-21, 23, 25-26, 29-30 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The newly added limitations of an antibody binding to the same epitope as MOC31/ BM2/BM7 have no clear support in the specification and the claims as originally filed. A comprehensive review of the specification revealed support for the MOC31/ BM2/BM7 antibodies as well as NrLu10-PE which binds to the same antigen but a different epitope as MOC31-PE, BM which binds to an epitope on the same antigen as BM7, MLuC1 which binds to a totally different antigen, the Lewis Y-antigen (pgs 3-4). Although Applicant states that "as the activity of an antibody as used in the invention is dependant on its specificity and as specificity is determined based on the epitope to which an antibody binds, the specification is, at least, enabling for antibodies binding to the same epitopes as antibodies MOC31 or BM2". It is noted that the issue raised here is not enablement, but rather that there is no guidance on, no suggestion of and no contemplation of antibodies binding to the same epitopes as MOC31/BM2/BM7 for use in the claimed method in the specification as originally filed. It is noted that applicant does not point to any support in the specification as originally filed for the newly added limitations. The subject matter claimed in claims 1, 6-8, 13-14, 20-21, 23, 25-26, 29-30 broadens the scope of the invention as originally disclosed in the specification.

8. Claims 1, 3, 6-8, 13-16, 18-23, 25-30 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 1, 3, 6-8, 13-16, 18-23, 25-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only a method of killing breast cancer cells and therefore the written description is not commensurate in scope with the claims drawn to a method of killing "other carcinoma cells expressing the same target antigens" wherein the antigens are targeted with MOC31 and BM1 or BM7.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Although drawn to the DNA arts, the findings of the courts in See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016 are relevant to the instant rejection. The courts found that adequate written description requires more than a mere statement that a particular limitation is part of the invention. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. In the instant

case the "other carcinoma cells expressing the same target antigens" have not been described. Although the specification teaches on page 11 that the epithelial antigen coded for by the GA 733-2 gene, EPG-2, is expressed by most of the carcinoma cells and therefore antibody against EPG-2 (MOC31) can be used in all cases involving carcinomas (for example breast cancer, colorectal cancer, prostate cancer, ovarian cancer, lung cancer and pancreatic cancer), the specification also teaches that the other antibody is directed to mucin, a mucus protein which is slightly different from one carcinoma type to another. Commonly the antigen can be described as proteins encoded by genes MUC-1, MUC-2 and MUC-3. It is noted that the claims are drawn to BM7 and BM2 which are anti-MUC-1 monoclonal antibodies. Other than breast cancer cells, the specification does not describe the "other carcinoma cells" that will be effectively treated by both MOC31 and BM7 or BM2 antibodies required to practice the method of the claims.

Furthermore, again drawn to the DNA arts but relevant to the instant claims, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Once again, only a single species of carcinoma cells that meet the limitations of the claims have been disclosed by the specification as originally filed.

Beyond the mere mention of "other carcinoma cells" to which MOC31 would be expected to bind, there is no disclosure of the carcinoma cells which would meet the limitations of the claims as currently constituted. This is insufficient to support the generic claims. Since, the specification does not provide an adequate written description of the "other carcinoma cells" required to practice the claimed invention, the specification fails to adequately describe the claimed method.

Therefore only a method of killing breast cancer cells, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

9. Claims 1, 3, 6-8, 13-16, 18-23, 25-30 are rejected under 35 USC 112, first paragraph as the specification is enabling only for claims limited to killing of breast cancer with MOC31 and BM7 or BM2 monoclonal antibodies, but does not reasonably provide enablement for killing other carcinoma cells expressing the same target antigens. The specification does not enable the skilled artisan to make or use the broadly claimed invention.

The specification teaches on page 11 that the epithelial antigen coded for by the GA 733-2 gene, EPG-2, is expressed by most of the carcinoma cells and therefore antibody against EPG-2 (MOC31) can be used in all cases involving carcinomas (for example breast cancer, colorectal cancer, prostate cancer, ovarian cancer, lung cancer and pancreatic cancer), the specification also teaches that the other antibody is directed to mucin, a mucus protein which is slightly different from one carcinoma type to another. Commonly the antigen can be described as

proteins encoded by genes MUC-1, MUC-2 and MUC-3. It is noted that the claims are drawn to BM7 and BM2 which are anti-MUC-1 monoclonal antibodies. The specification further teaches that the binding profile of several antibodies to breast cancer cell lines and tumor materials had been examined by others and partly confirmed by the instant inventors. The antibodies which bind to a large percent of breast cancer cells and not to normal cells were conjugated to PE and assayed for breast cancer kill ability (p. 5, lines 19-25). One cannot extrapolate the teaching of the specification to the enablement of the claims. Although it is clear that both anti-EPG-2 antibody MOC31 and anti-MUC-1 antibody BM7/BM2 will bind to and kill breast cancer cells, no other carcinoma marker profiles were done, neither the specification nor the art of record teaches what other carcinoma cells express the two markers in a way that both MOC31 and BM7/BM2 will kill those cells and in the absence of further guidance in the specification as originally filed, it cannot be predicted that any other carcinoma cells would express sufficient MUC-1 marker so that the invention would function as claimed. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the invention will function as claimed with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

10. No claims allowed.

11. All other objections and rejections recited in the Paper mailed August 21, 2003 are hereby withdrawn.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
March 12, 2004